80. The device of claim 64, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the labeled specific binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.

81. The device of claim 64, wherein the macroporous body comprises a plastic material.

82. The device of claim 64, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

doesn't get priority

B2 cancel

83. The device of claim 26, further comprising a second dry porous carrier strip arranged such that the flow path extends from the macroporous body into both carrier strips, in parallel, said second carrier strip having a binding reagent immobilized thereon or therein, said binding reagent on the second porous strip being selected from binding reagents specific for the analyte and binding reagents specific for a different material of interest.

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REMARKS

This paper is filed in response to the Restriction Requirement mailed January 17, 2002 for the above-captioned application. Applicants request an extension of time sufficient to make this submission timely and enclose the appropriate fee. The Commissioner is authorized to charge and additional fees or credit any overpayments to Deposit Account No. 15-0610.

Applicants have amended the first page of the application to more clearly and completely reflect the chain of priority under 35 USC 120 and 371 for this application. Entry of a corrected chain of priority into the PALM and PAIR systems, and issuance of a corrected filing receipt are requested

The Examiner indicated in the restriction requirement that there were two groups of claims. Both groups of claims have been canceled and a new set of claims has been added. These claims are all dependent from a single claim, and Applicants believe that they are properly considered as a single invention. Applicants attach as Exhibit A a table showing where support for each new claim can be found in the specification and in the priority document. A copy of the priority document with annotations indicating the differences between that document and the US application is attached as Exhibit B.[1]

Applicants thank the Examiner for taking the time for a meeting with their attorney. This paper will summarize that interview.

During the interview, Applicants' attorney pointed out that the application was subject to the new 102(e) provisions, and that the May reference relied on in the parent case would therefore be unavailable as art against this application. Three other references were discussed: US Patents Nos. 5,591,645 of Rosenstein, 4,943,522 of Eisinger and 4,861,711 of Friesen.

As defined in the newly submitted claims, the invention is an for performing an assay for an analyte in a liquid sample. The device has a housing in which there are disposed: a porous carrier strip which has an analyte-binding reagent on or in it; and a macroporous body which contains a labeled analyte-specific binding reagent. The labeled specific binding reagent has a directly visible particulate label and is freely mobile in the macroporous body when it is wetted with the liquid sample.

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[1] It is noted that a lack of support for the invention in the priority document could render the publications of the priority documents of the May reference, as presumptive prior art under 35 USC 102(a), and may make other art available. Thus, the Examiner is requested to confirm that the claim for priority with respect to the presented claims is valid.

The Eisinger reference discloses an immunochromatography device. An optional component of this device is a pad (110, 210) which is described as having two functions. First, it can contain an enzyme reagent. Second it can act as a filter. The present claims are different from the device as disclosed in Eisinger for a variety of reasons. The reagent in the Eisinger pad is an enzyme, not a particulate label. Furthermore, since the Eisinger pad is intended to act as a filter there is no reason to conclude that it would allow a particulate label to be freely mobile. Indeed, the filtration function, i.e, the capturing of particles, if the very antithesis of free mobility. The disclosure of Friesen is similar to that of Eisinger. As reflected in Col. 2, line 54 - Col. 3, line 5, an absorptive material can be provided for sample application prior to a chromatography section. This absorptive material can serve the function of filtration and providing reagents. However, there is no disclosure of providing a teaching of particulate labels within this absorptive material, and no suggestion of using such materials which might well be trapped in the filter. Thus, Applicants respectfully submit that neither Eisinger nor Friesen anticipates that newly presented claims or renders them obvious.

The Rosenstein patent describes a dip stick device which is described as having four "portions", including a portion A which includes a tracer (label plus binding moiety), and a portion B which contains an immobilized capture reagent for the analyte. There is no specific disclosure apart from the example which idenify these portions as being made from different materials. However, in the example (Col. 7) the portion A is said to be made from dry Sephadex G50 fine-grade bead formed gel which is applied to an adhesive layer on a support, while portion B is said to be a ntircellulose square applied to the adhesive layer. The label employed in this example in Rosenstein is a dye-containing liposome tethered to an antibody.

Applicants submit that Rosenstein is also different from the claimed invention. Although the dye-containing liposome could be considered a particulate label, the region of Sephadex beads is not fairly characterized as a macroporous body within the scope of the claims. As is apparent from the present disclosure, this "body" is an integrated structure. In contrast, the Sephadex beads are simply dust applied to the adhesive. Furthermore, it is not clear what properties these beads have. Conventionally, Sephadex G50 is a size-exclusion gel used in a liquid swelled state. In this state, the gel has pores of different sizes are present to slow the

passage of materials through the gel. These pores are sized to retard but ultimately allow the passage of DNA molecules. Since DNA molecules are small compared to particulate labels, there is no teaching or suggestion that a particulate label would be "freely mobile" within such a material. However, there is no teaching in Rosenstein that the beads are swelled prior to placement in the device (they are described as "dry"), or that they have time to achieve a swelled state during use as a dipstick. Thus, it is impossible to describe the actual pore structure of Rosenstein. Given this ambiguity, Applicants submit that Rosenstein cannot be taken as teaching or fairly suggesting a dipstick with a first portion in which a particulate label is freely mobile.

In view of the foregoing remarks, Applicants submit that the newly presented claims are in form for allowance. Early consideration of this application is requested in view of its early effective filing date. To facilitate this consideration and early allowance, Applicants enclose a form PTO-1449 listing the references of record in the parent case, and copies of the patent references. Applicants' new attorney has not received copies of the articles as part of the transfered files. Accordingly, consistent with the provisions of 37 CFR § 1.98, the Examiner is requested to look for copies of these references in the parent case, US Patent No. 6,352,862.

Applicants also enclose a terminal disclaimer over the issued parent case, US Patent No. 6,352,862 and the appropriate fee.

Should the Examiner have any questions which may be addressed by a telephonic interview, she is encouraged to call the undersigned.

Respectfully submitted,

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Attorney for Applicants
PTO Reg. No. 32,038

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Exhibit A - Table Showing Support for Claims

| Claim | Support in Specification | Support in Priority Document |
|---|---|---|
| 26 | Page 2, line 19- Page 3, line 2; Page 4, lines 5-7 | Page 2, lines 18-36; Page 3, lines 24-26 |
| 27, 46, 65 | Page 5, lines 7-9 | Page 3, lines 27-29 (non-metallic colloids not in priority document) |
| 28, 47, 66 | Page 5, lines 5-6 | Page 4, line 22 |
| 29, 48, 67 | Page 5, lines 9-10 | Page 4, line 25 |
| 30, 49, 68 | Page 5, line 10 | Page 4, line 26 |
| 31, 50, 69 | Page 4, line 29 | Page 4, line 9 |
| 32, 51, 70 | Page 3, lines 18-19 | Page 3, lines 1-2 |
| 33, 52, 71 | Page 3, lines 18-19 | Page 3, line 3 |
| 34, 53, 72 | Page 7, lines 12-14 | Page 6, lines 19-20 |
| 35, 54, 73 | Page 7, lines 16-24 | Page 6, lines 23-31 |
| 36, 55, 74 | Page 9, lines 6-10 | Page 8, lines 13-17 |
| 37, 56, 75 | Page 9, lines 12-15 | Page 8, lines 17-22 |
| 38, 57, 76 | Page 9, lines 27-30 | Page 8, lines 34-36 |
| 39, 58, 77 | Page 9, line 16-17 | Page 8, line 24 |
| 40, 59, 78 | Page 16, lines 23-27 | Page 15, line 28-34 |
| 41, 60, 79 | Page 8, lines 1-9; Page 10, lines10-17 | Page 7, lines 8-16, Page 9, lines 5-30 |
| 42 , 61, 80 | Page 11, line 31-Page 12, line 2 | Page 11, lines 1-8 |
| 43, 62, 81 | Page 5, lines 8-10 | Page 4, line 24 |
| 44, 63, 82 | Page 7, lines 4-10 | Page 17, lines 1-23 |
| 45 | Page 10, lines10-24 | Page 9, lines 5-30 |
| 64 | Page 10, lines 24-27 | Page 9, lines 30-33 |
| 83 | Page 14, lines 24-35 | |

Substitute for form 1449

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Application No.: 09/944,389
Applicant: Davis
Filing Date: 09/04/2001
Title: Assays



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